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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,580	10/06/2003	Glenn H. MacKal	380804.00116	6851
34802	7590	10/31/2008		
HOLLAND & KNIGHT LLP			EXAMINER	
ATTN: STEFAN V. STEIN/ IP DEPT.			CARTAGENA, MELVIN A	
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TAMPA, FL 33601-1288			ART UNIT	PAPER NUMBER
			3754	
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			10/31/2008 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/681,580

Applicant(s)

MACKAL ET AL.

Examiner

MELVIN A. CARTAGENA

Art Unit

3754

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5, 6 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6 and 9 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CD/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. Claims 1, 3, 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,308,494 to R. J. Licher in view of US 3,279,995 to Reid.

Licher discloses an automatic inflator Comprising a body (see Fig. 3) for receiving a dissolvable annular pill (53, 163, 164, and other ref. nos. in other embodiments) including an upper surface and a lower surface with an undulating configuration in various embodiments (note also the serrations and apertures in various embodiments). Licher also discloses the peaks and troughs (claim 2), multiple surfaces with undulations (claim 3), undulations out of phase with each other (claim 5, see Fig. 11), the undulations extending radially (claim 6), and a center hole (claim 9). Licher no longer anticipates the claims, as the surfaces no longer have multiple

undulating configurations extending parallel to the plane of the surface that is transverse to an axis of the pill.

Reid discloses how the shape of the dissolvable annular pill can be designed with concave surfaces and convex protuberances to control the rate at which the pill would dissolve, see column 2, lines 1-6.

Therefore, Licher does not disclose the exact shape of the pill as set forth in the claims. However, Licher also recognizes that the shape of the dissolvable pill is a results effective variable, i.e. a variable that achieve a recognized result. In the instant case, the shape is chosen to have a greater surface area so that the pill dissolves quickly (see column 3, lines 29- 43) as taught by Reid. If one of ordinary skill in the art wants the pill to dissolve more quickly, they will choose a shape with greater surface area (i.e. more undulations) and if the artisan wants the pill to dissolve less quickly, they will choose a shape with a lesser surface area. Since the prior art recognizes the shape as a results-effective variable, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have chosen the shapes set forth in the claims, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (see MPEP 2144.05).

Allowable Subject Matter

4. Claim 5 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. Applicant's arguments, see amendment, filed July 28, 2008, with respect to the written description requirements, have been fully considered and are persuasive. The rejection under 35 U.S.C. 112, first paragraph of claim 5 has been withdrawn.

Applicant's arguments filed July 28, 2008 have been fully considered but they are not persuasive. Applicant argues that not all surfaces of the pill of Licher are exposed to the increased absorption. The device of Reid discloses how the shape of the pill can be designed and manufactured to obtain the optimum desired dissolving rate depending on the application of the pill.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELVIN A. CARTAGENA whose telephone number is (571)272-4924. The examiner can normally be reached on T-F (7:30AM to 6:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. A. C./
Examiner, Art Unit 3754

/Kevin P. Shaver/
Supervisory Patent Examiner, Art Unit 3754